



OCT 18 2010

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In Re: Patent Term Extension
Application for
U.S. Patent No. 7,037,917

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 7,037,917, which claims the human drug product INTELENCE® (etravirine), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 404 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 404 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 22, 2009 (74 Fed. Reg. 24014). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,050 - 1,608) + 185 \\ &= 404 \text{ days (1.1 years)}\end{aligned}$$

Since the regulatory review period began December 7, 2001, before the patent issued (May 2, 2006), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From December 7, 2001, to and including May 2, 2006; is 1,608 day; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 7,037,917

Granted:	May 2, 2006
Original Expiration Date ¹ :	November 1, 2019 ²
Applicant:	Bart De Corte et al.
Owner of Record:	Janssen Pharmaceutica, N.V.
Title:	HIV Replication Inhibiting Pyrimidines
Product Trade Name:	INTELENCE® (etravirine)
Term Extended:	404 days
Expiration Date of Extension:	December 11, 2020

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Mail Stop Hatch-Waxman PTE	By FAX:	(571) 273-7755
	Commissioner for Patents		
	P.O. Box 1450		
	Alexandria, VA 22313-1450.		

¹Subject to the provisions of 35 U.S.C. § 41(b).

²Applicant indicates that the expiration date of the present patent is November 5, 2019, by virtue of the accrual of 4 days of Patent Term Adjustment under 35 U.S.C. 154(b) due to delays in prosecution before the USPTO. However, the expiration date is November 1, 2019, because a patent, terminally disclaiming a portion of the term over another commonly-owned reference patent for the purposes of obviating an obviousness-type double patenting rejection, cannot—in compliance with 37 C.F.R. § 1.321—have an expiration date which extends beyond the expiration date of the reference patent, even if patent term adjustment had accrued. See 35 U.S.C. § 154(b)(2)(B).

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: INTELENCE® (etravirine)
FDA Docket No.: FDA-2008-E-0307

Attention: Beverly Friedman